

REMARKS

Claim 4 has been amended to incorporate the limitation of part of claim 50, as previously pending, i.e., to exclude SEQ ID NO:50.

No new matter has been added.

Rejection Under 35 U.S.C. 112, First Paragraph**Written Description**

The Examiner maintained the rejection of claims 1, 2, 11, 44-50 and 52-54 as lacking an adequate written description. Applicant respectfully traverses the rejection.

The Examiner believes that there is no correlation between structure and function for the claimed polypeptides. Thus the Examiner asserts that not every peptide fragment of SEQ ID NO:1 would bind HLA-A2 or elicit a T cell response.

While Applicant disagrees with the Examiner as to the correlation of structure and function, even assuming (for the sake of argument) the Examiner is correct, claims 1, 2, 50 and 52-54 should be considered as adequately described because the claims contain functional limitations on the scope of the claimed polypeptides. Thus, the skilled person will have a clear idea that Applicant is claiming just what has been invented and not more. Furthermore, whether a particular polypeptide falls within the scope of the claim can be ascertained readily by the skilled person. Thus, the skilled person can understand that Applicant invented the claimed invention, is required for an adequate written description. Vas-Cath v. Mahurkar, 35 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). The Examiner is reminded that a recitation of exact structures is not the only way to provide an adequate written description of a claimed invention.

In response to the Examiner's assertion that the Capon v. Eshhar case is not applicable, Applicant respectfully disagrees. That case is on point with the current situation, since applicant is claiming polypeptides of which a part of the sequence is known (i.e., part of SEQ ID NO:1).

Claims 11 and 44-49, on the other hand, depend from claim 4 and therefore require the presence of the nonapeptide of claim 4 with specific amino acids at the second and last amino acid residue. Applicant asserts that this is sufficient structural information to clearly convey to the person of ordinary skill in the art what Applicant has invented, and therefore should be sufficient to avoid a written description rejection of these claims. This is true particularly because the sequence must also be a fragment of SEQ ID NO:1, thereby specifying the remaining amino acids in the nonapeptide. This is a limited group of peptides of common structure that are readily recognizable by the skilled person, since it is possible for the skilled person to write down in a listing exactly which nonapeptides meet the requirements of claim 4, and thus are included in the claimed invention.

Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1, 2, 11, 44-50 and 52-54 as lacking an adequate written description.

Enablement

The Examiner maintained the rejection of claims 1, 2, 4, 5, 9, 11, 42-50 and 52-54 as not enabled by the specification. Applicant respectfully traverses the rejection.

Applicant asserts that this rejection is misplaced, because the Examiner uses the wrong basis for rejecting the claims.

All of the claims are directed to polypeptides that are fragments of MAGE-10, SEQ ID NO:1. Many of the claims are nonapeptides in which the amino acids are specified by virtue of the requirement that they are fragments of SEQ ID NO:1 and have certain amino acids at the second and last positions.

The Examiner focuses on the unpredictability of using the polypeptides for producing antibodies or CTLs for diagnosis or treatment of cancer. The Examiner states that the problem is that the expression on cancer cell lines does not predictably extrapolate to expression on cells of a cancer tissue. Thus, according to the Examiner, one cannot predict that the polypeptide would be adequately expressed on primary cancer cells "such that it could be recognized by antibodies or CTLs specific for SEQ ID NO:1." (see paragraph spanning pages 6 and 7 of the Office Action)

The Examiner also states that one could not predict whether the conformation of the claimed polypeptide would be the same as SEQ ID NO:1 and expose on its surface the appropriate sequence for recognition by B cells or T cells. The reason provided for this assertion is that the effect of the amino acids attached to the described nonapeptides on the conformation is unpredictable. (see second paragraph on page 7 of the Office Action)

The Examiner also asserts that cancer diagnosis and treatment is unpredictable. This assertion appears to be irrelevant to the present claims to polypeptides, however.

With respect to nonapeptides, the Examiner states that even though the peptides are known as fragments of SEQ ID NO:1, it would have been undue experimentation to screen for the claimed sequences. This assertion is based on the alleged unpredictability that the peptides could elicit T cell responses or have sufficient affinity for HLA-A2.

This aspect of the rejection is inapplicable to at least claims 4, 5, 9-11, 42-49 because these claims all define the sequences specifically.

For the other claims, Applicant notes that the Examiner's assertion does not adequately take into consideration the fact that any experimentation needed is entirely routine for the person of ordinary skill in this art. Moreover, the specification provides more than adequate guidance to make and/or use the claimed invention. Testing a finite and well-defined set of polypeptides for

HLA-A2 binding and/or CTL stimulation is not require an exercise of undue experimentation; it is simply routine experimentation in this art.

The Examiner's citation of the Rochester v. Searle case is inapposite. In that case, the patentee claimed methods for inhibiting a particular enzyme activity by administering compounds of undefined and unknown structure. In the instant application, the claims are not directed to methods of treatment and further the polypeptides claimed each are identified with sufficient structural detail to permit the skilled person to understand the scope of the claims, without undue experimentation but with a reasonable expectation of success.

Finally, Applicant reiterates that the claimed invention is directed to isolated polypeptides that have uses other than the use singled out by the Examiner. Preparation of the claimed polypeptides, given the sequences and experimental guidance provided in the specification, would not require undue experimentation by the skilled person. Indeed, such preparation is entirely routine in the art, as evidenced by the long history of tumor rejection antigen peptides that is mentioned in the background section of the specification on pages 1-3.

Accordingly, Applicant respectfully request that the Examiner withdraw the rejection of the claims as not enabled.

Rejection Under 35 U.S.C. 102(e)

The Examiner maintained the rejection of claims 4, 11, 42-43 as anticipated by US 6,682,731. Applicant respectfully requests reconsideration of the rejection.

Applicant has amended claim 4 to exclude SEQ ID NO:50 from the claimed subject matter. Claims 11, 42 and 43 all depend from claim 4 and thus also exclude SEQ ID NO:50.

Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of claims 4, 11, 42-43 as anticipated by US 5,912,143.

Claim Objections

The Examiner objected to claims 1-2, 44-50 and 52-54 because claims 1 and 2 allegedly are confusing.

Specifically, the Examiner stated that "It is not clear how the claimed polypeptide, such as the nonapeptide SEQ ID NO:42, is not that set out *in* SEQ ID NO:1." (emphasis in original)

Applicant's response is that claims 1 and 2 specifically exclude SEQ ID NOs:1 and 2. SEQ ID NO:42 is not either of SEQ ID NOs:1 or 2, and therefore is not excluded from the scope of the claims.

Accordingly, Applicant respectfully requests that the Examiner withdraw the objection to claims 1-2, 44-50 and 52-54.

Rejection Under 35 U.S.C. 102(b)

The Examiner rejected claims 1-2, 4, 11, 42, 44-45, 47-48, 50, 52-54 as anticipated by Registry Number 53665-55-7, as taught by Okada et al., 1974 (Tetrahedron, 30(10): 1175-85).

Based on the rejoinder of the species in which the N-terminal amino acid is L and the C-terminal amino acid is I, the Examiner has rejected as anticipated claims 1-2, 4, 11, 42, 44-45, 47-48, 50 and 52-54. The rejection is based on a peptide having Registry Number 53665-5-7 (VLAVALSLSI) as described in Okada et al., Tetrahedron 30(10):175-1185, 1974.

This peptide does have a Leu as the amino acid adjacent to the N-terminal amino acid and a Leu as the C-terminal amino acid. However, it does not otherwise correspond to an unbroken sequence of amino acids from SEQ ID NO:1 (MAGE-10). Because all of the pending claims (except claim 9, which claims a specific sequence) require the claimed polypeptide to be an

unbroken sequence of amino acids from SEQ ID NO:1, Registry Number 53665-55-7, as taught by Okada does not anticipate the claimed invention. Stated another way, the Registry Number 53665-55-7 reference does not provide a polypeptide that includes an unbroken sequence of amino acids from SEQ ID NO:1 with the aforementioned specific amino acid residues adjacent to the N-terminus and at the C-terminus. Therefore the Registry Number 53665-55-7 reference cannot anticipate the claimed invention.

Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1-2, 4, 11, 42, 44-45, 47-48, 50, 52-54 as anticipated by Registry Number 53665-55-7, as taught by Okada et al., 1974 (Tetrahedron, 30(10): 1175-85).

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,


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